Recommendations by the Quality Task Group (54): Performance Requalification for No Particular Reason

The queries frequently received from users indicate that apparently there is uncertainty as to what performance requalification should exactly entail and how often it should be carried out.

While the ➜ **STANDARD** recommends yearly performance requalification, we believe that this should be determined by the number of batches/washer-disinfector (WD) because some establishments operate on the basis of two or three shifts, while in other institutions the WDs are not used as extensively.

➜ **STANDARD EN ISO 15883** recommends yearly performance requalification.

The authors of the DGKH, DGSV and AKI Guideline for validation of automated cleaning and disinfection processes for heat-sensitive medical devices have compiled a joint recommendation on this topic. This will be published at a later date together with further supplements to the Guideline.

The procedure described here refers to performance requalification (PRQ) assuming that no changes have been made warranting "performance requalification for a particular reason" (e.g. new process chemicals, other loading configurations, changes to the process). Standard EN ISO 15883-1 recommends annual performance requalification.

1. The operator must be in possession of the following confirmatory documentation/checklists:

Documentation/Checklists that must be provided by the operator

a. Maintenance must be carried out within 4 – 6 weeks before performance requalification.

b. If all loading trolleys and their connections to the water supply source have not been checked as part of the maintenance exercise, confirmation of successful functional testing, including a check of the pressure, must be provided to that effect (issued within a maximum of 4 – 6 weeks).

c. If calibration, and any necessary adjustments of all WD sensors, is not carried out as part of performance requalification, proof must be furnished of calibration and adjustment, issued within a maximum of 4 – 6 weeks.

2. The *release documentation (batches) and routine checks* since the last performance requalification must be checked by the operator. The operator and validator shall conduct joint assessment and on that basis define the measures and scope of performance requalification.

The release documentation and routine checks must be checked.

3. *At least 5 test Crile instruments* shall be used and tested in one programme. If *hollow devices*, which are viewed as being particularly critical, are being decontaminated they must be inspected at the time of performance requalification. At least 3 hollow devices harbouring an everyday soil (Veress needle, shaft of an MIS scissors, suction device) shall be subjected to visual inspection and then tested and evaluated with the Biuret/BCA method.

Hollow devices must be inspected if they are being decontaminated.

The results must not show any negative deviations from the results of the initial validation.

Note: There is no need to check every programme and every load configuration during performance requalification if proof of the basic suitability of the programmes/process cycles in use was provided during initial validation. If it comes to light that the initial validation was incomplete, the missing tests must be carried out by the latest at the time of the first performance requalification.

Missing tests of the initial validation must be carried out at the time of the first performance requalification.

In the course of time, it is primarily the physical parameters, such as the water level, pressure, temperature, dosage of process chemicals, which can change and equally affect all programmes and loads. The selected and described programmes are checked for any changes, and any deviations are recorded. Mechanical deviations will come to light during maintenance and when checking the loading trolleys.

4. The ***measuring curves and test results*** are compared with those obtained for the initial validation. In the event of any deviations, the checked programme must be tested repeatedly, using other programmes if necessary. If the negative deviations continue to persist, the cause of these must be investigated and remedial measures taken.

In the event of deviations from the result of the initial validation, the checked programme must be tested repeatedly; the cause must be investigated.